IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	MDL NO. 3094 THIS DOCUMENT RELATES TO ALL CASES JUDGE KAREN SPENCER MARSTON
CANDIS FOSTER, *Plaintiff,* v. ELI LILLY AND COMPANY, *Defendant.*	COMPLAINT AND JURY DEMAND CIVIL ACTION NO.: _____

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff files this Complaint pursuant to the Direct Filing Order and is to be bound by the rights, protections and privileges, and obligations of that Direct Filing Order and other Orders of the Court. Further, in accordance with the Direct Filing Order, Plaintiff hereby designates the United States District Court for the Northern District of Georgia as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this selection based upon one (or more) of the following factors (check the appropriate box(es)):

X Plaintiff currently resides in Rome, Georgia.

X Plaintiff purchased and used Defendant's product in Rome, Georgia.

__ The Original Venue is a judicial district in which Defendant _____ resides, and all Defendants are residents of the State in which the district is located (28 USC § 1391(b)(1)).

X The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specifically (28 USC § 1391(b)(2)): Plaintiff was diagnosed with a bowel obstruction in Rome, Georgia.

__ There is no district in which an action may otherwise be brought under 28 USC § 1391, and the Original Venue is a judicial district in which Defendant _____ is subject to the Court's personal jurisdiction with respect to this action (28 USC § 1391(b)(3)).

__ Other reason (please explain): _____.

Plaintiff, CANDIS FOSTER, by Plaintiff's attorney, Parvin Aminolroaya of Seeger Weiss, LLP, upon information and belief, at all times hereinafter mentioned, alleges as follows

JURISDICTION AND VENUE

1. The Original Venue has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Plaintiff resides, which is Georgia.

2. The Original Venue has personal jurisdiction over Defendants, consistent with the United States Constitution and Ga. Code Ann. § 9-10-91 (Georgia's "long arm" statute), as Plaintiff's claims arise out of Defendants' transaction of business and the tortious acts within the State of Georgia, and by virtue of Defendants' substantial, continuous, and systematic contacts with the State of Georgia unrelated to Plaintiff's claims.

NATURE OF THE CASE

3. This is an action for damages suffered by Plaintiff, Candis Foster, who was severely injured as a result of Plaintiff's use of Mounjaro, an injectable prescription medication that is used to control blood sugar in adults with type 2 diabetes.

4. Mounjaro is also known as tirzepatide. Mounjaro works by targeting the body's receptors for GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1).

5. Mounjaro belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

6. Defendant acknowledges that gastrointestinal events are well known side effects of the GLP-1RA class of drugs.[1] However, Defendant has downplayed the severity of the gastrointestinal events caused by Mounjaro, never, for example, warning of the risk of intestinal/bowel obstruction, and its sequalae.

7. Intestinal/bowel obstruction refers to a partial or total blockage of the intestine, preventing food, liquids or gas from passing through.[2] This may cause the intestine to rupture, leaking harmful contents into the abdominal cavity, or "the blocked parts of the intestine can die, leading to serious problems."[3] Symptoms of intestinal obstruction include cramps, abdominal pain, loss of appetite, constipation, vomiting, inability to have a bowel movement or pass gas, and swelling of the abdomen.[4]

PARTY PLAINTIFF

8. Plaintiff, Candis Foster, is a citizen of the United States, and is a resident of the State of Georgia.

9. Plaintiff is 44 years old.

10. Plaintiff used Mounjaro from on or about July of 2022 to on or about June of 2023.

11. Plaintiff's physician(s) ("prescribing physician(s)") prescribed the Mounjaro that

[1] *See, e.g.*, CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (visited on 9/26/23).
[2] Kristeen Moore, E. Mimi Arquilla, *Bowel Obstruction and Blockage*, Healthline (March 15, 2023), available at https://www.healthline.com/health/intestinal-obstruction (last visited on 10/16/23).
[3] Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/symptoms-causes/syc-20351460 (last visited on 10/16/23); *see also* Kristeen Moore, E. Mimi Arquilla, *Bowel Obstruction and Blockage*, Healthline (March 15, 2023), available at https://www.healthline.com/health/intestinal-obstruction (last visited on 10/16/23).
[4] Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/symptoms-causes/syc-20351460 (last visited on 10/16/23).

was used by Plaintiff.

12. As a result of using Mounjaro, Plaintiff was caused to suffer from intestinal/bowel obstruction, and its sequelae and, as a result, sustained severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

13. As a result of using Mounjaro, Plaintiff was caused to suffer from intestinal/bowel obstruction, and its sequelae, which resulted in, for example, nausea, vomiting, and abdominal pain.

PARTY DEFENDANT

14. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with a principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

15. Eli Lilly designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed Mounjaro and is identified on the drug's label.[5]

FACTUAL BACKGROUND

A. FDA's Approval of Mounjaro

16. On September 14, 2021, Eli Lilly submitted NDA 215866 Mounjaro (tirzepatide) injection as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On May 13, 2022, the FDA approved NDA 215866.[6]

17. On May 13, 2022, Eli Lilly announced the FDA's approval of NDA 215866 Mounjaro (tirzepatide) injection as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. In the press release, Eli Lilly disclosed a safety summary and provided

[5] Mounjaro prescribing information, available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d2d7da5d-ad07-4228-955f-cf7e355c8cc0 (last visited on 8/24/23).

[6] FDA Approval Letter for NDA 215866 (Mounjaro) available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/215866Orig1s000ltr.pdf (last visited on 8/24/23).

a link to the Medication Guide and Prescribing Information, but ileus and intestinal obstruction were not identified as risks.

B. Eli Lilly's Marketing and Promotion of Mounjaro

18. On May 13, 2022, Eli Lilly announced approval of Mounjaro, proclaiming "Mounjaro's safety … in a broad range of adults with type 2 diabetes."[7]

19. At all relevant times, Eli Lilly was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Mounjaro.

20. On October 6, 2022, Eli Lilly announced that the FDA had "granted Fast Track designation for the investigation of tirzepatide" to treat obese or overweight adults.[8]

21. According to a recent publication, in fall 2022, analysts at UBS projected that Mounjaro could reach peak sales of $25 billion, asserting Eli Lilly's position in the multibillion-dollar obesity market.[9]

22. In March 2023, it was reported that Eli Lilly kicked off a full-scale consumer campaign for Mounjaro after launching a digital campaign in January, including a 75-second TV spot supporting Mounjaro aired on FOX on February 12, the same day as Super Bowl LVII.[10]

23. On April 11, 2023, the New York Times reported that Mounjaro was "gaining attention, with many people using it off-label to lose weight." The article described research which

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[7] *FDA approves Lilly's Mounjaro™ (tirzepatide) injection, the first and only GIP and GLP-1 receptor agonist for the treatment of adults with type 2 diabetes*, Cision PR Newswire (May 13, 2022) available at https://www.prnewswire.com/news-releases/fda-approves-lillys-mounjaro-tirzepatide-injection-the-first-and-only-gip-and-glp-1-receptor-agonist-for-the-treatment-of-adults-with-type-2-diabetes-301547339.html (last visited on 8/24/23).

[8] *Lilly Receives U.S. FDA Fast Track designation for tirzepatide for the treatment of adults with obesity, or overweight with weight-related comorbidities* (October 6, 2022) available at https://investor.lilly.com/news-releases/news-release-details/lilly-receives-us-fda-fast-track-designation-tirzepatide (last visited on 8/24/23).

[9] Munger L, BioSpace, *Eli Lilly and Novo Nordisk Face Off in Lucrative Obesity Market* (May 30, 2023) available at https://www.biospace.com/article/eli-lilly-and-novo-nordisk-face-off-in-lucrative-obesity-market/ (last visited on 8/24/23).

[10] O'Brien J, Medical Marketing and Media, *Eli Lilly kicks off consumer campaign for diabetes drug Mounjaro* (March 9, 2023) available at https://www.mmm-online.com/home/channel/campaigns/eli-lilly-kicks-off-consumer-campaign-for-diabetes-drug-mounjaro/ (last visited on 8/24/23).

"found that Mounjaro may be even more powerful" than Ozempic, which it reported had recently "steamrollered through TikTok, talk shows and tabloids as people raved about using it off-label to lose weight." Although Eli Lilly denied promoting or encouraging "the off-label use of any of our medicines[,]" it was obvious to Eli Lilly and others in the industry that Mounjaro was following Ozempic's rising popularity for its weight loss effects. Furthermore, the same article also noted Eli Lilly's October announcement regarding the FDA's fast-track designation for its review of tirzepatide.[11]

C. The Medical Literature and Clinical Trials Gave Eli Lilly Notice of Intestinal/Bowel Obstruction and Its Sequelae Being Causally Associated with GLP-1RAs.

24. As previously noted, Mounjaro (tirzepatide) belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

25. Medications within the GLP-1RA class of drugs mimic the activities of physiologic GLP-1, which is a gut hormone that activates the GLP-1 receptor in the pancreas to stimulate the release of insulin and suppress glucagon.[12]

26. Because the risks of intestinal/bowel obstruction, and its sequelae are common to the entire class of drugs, any published literature regarding the association between intestinal/bowel obstruction, and its sequelae and *any* GLP-1RA (such as tirzepatide, exenatide, liraglutide, albiglutide, dulaglutide, lixisenatide, and semaglutide) should have put Defendant on notice of the need to warn patients and prescribing physicians of the risks of intestinal/bowel obstruction, and its sequelae associated with this drug.

27. As early as 2010, a study published in The Journal of Clinical Endocrinology &

[11] Blum D, *The Diabetes Drug That Could Overshadow Ozempic,* The New York Times (published April 11, 2023, updated June 24, 2023) available at https://www.nytimes.com/2023/04/11/well/live/ozempic-mounjaro-weight-loss-diabetes.html (last visited on 8/24/23).
[12] Hinnen D, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30(3) Diabetes Spectr., 202–210 (August 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/ (visited on 9/26/23).

Metabolism concluded that GLP-1 slows gastric emptying.[13]

28. Defendant knew or should have known of the risks of intestinal/bowel obstruction, and its sequelae from the clinical trials, medical literature, and case reports.

29. In 2012, Japan's Pharmaceutical and Food Safety Bureau advised that "[i]ntestinal obstruction may occur" in patients taking the GLP-1RAs exenatide and liraglutide, and as a result "[p]atients should be carefully monitored, and if any abnormalities including severe constipation, abdominal distention, persistent abdominal pain, or vomiting are observed, administration of [the drugs] should be discontinued, and appropriate measures should be taken." The agency further reported that in the previous 1 year and 8 months, three cases of intestinal obstruction had been reported in liraglutide users "for which causality [associated with] the drug could not be ruled out."[14]

30. A 2013 article by a co-author who had participated on Novo Nordisk advisory boards, explained that "[a]cute, intravenous infusion of GLP-1 (in pharmacological doses) slows gastric emptying markedly in both healthy subjects and patients with type 2 diabetes in a dose-dependent manner by mechanisms that include relaxation of the proximal stomach, reduction of antral and duodenal motility, and an increase in pyloric tone, and which involve vagal pathways."[15]

31. In 2013, the European Medicines Agency's Pharmacovigilance Risk Assessment

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[13] Deane AM et al., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95(1) J Clinical Endo Metabolism, 225-221 (January 1, 2010), available at https://academic.oup.com/jcem/article/95/1/215/2835243 (last visited on 9/26/23); American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (last visited on 9/26/23).

[14] Pharmaceuticals and Medical Devices Safety Information No. 291, Pharmaceutical and Food Safety Bureau (June 2012), available at https://www.pmda.go.jp/files/000153459.pdf (last visited Nov. 16, 2023).

[15] Marathe C, *Relationships Between Gastric Emptying, Postprandial Glycemia, and Incretin Hormones*, 36(5) Diabetes Care, 1396-1405 (April 13, 2013), available at https://diabetesjournals.org/care/article/36/5/1396/29534/Relationships-Between-Gastric-Emptying (last visited October 26, 2023).

Committee (PRAC) received a "safety communication from the Japanese medicines agency … reporting intestinal obstruction in patients treated with" GLP-1RAs. As a result, PRAC searched EudraVigilance "for intestinal obstruction and related terms" and retrieved 59 cases for the GLP-1RAs exenatide and liraglutide, leading PRAC to recommend appropriate amendments to the product information.[16] Notably, Novo Nordisk manufactures and markets liraglutide under the brand names Saxenda and Victoza.

32. A 2016 trial funded by Novo Nordisk measuring semaglutide and cardiovascular outcomes in patients with type 2 diabetes found more gastrointestinal disorders in the semaglutide group than in the placebo group, including a severe adverse event report of impaired gastric emptying with semaglutide 0.5 mg together with other serious gastrointestinal adverse events such as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.[17]

33. Two subjects in a semaglutide trial pool by Novo Nordisk reported moderate adverse events of impaired gastric emptying and both subjects permanently discontinued treatment due to the adverse events. Three subjects also reported mild adverse events of impaired gastric emptying in the semaglutide run-in period of trial 4376.

34. A study published in 2017 evaluated the effect of GLP-1RAs on gastrointestinal tract motility and residue rates and explained that "GLP-1 suppresses gastric emptying by inhibiting peristalsis of the stomach while increasing tonic contraction of the pyloric region." The study authors concluded that the GLP-1RA drug liraglutide "exhibited gastric-emptying delaying

[16] European Medicine Agency, Pharmacovigilance Risk Assessment Committee, minutes of meeting (January 7-10, 2013) available at https://www.ema.europa.eu/en/documents/minutes/minutes-prac-meeting-7-10-january-2013_.pdf (last visited 10/20/23).
[17] Marso, SP, et al., Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes, N. Eng. J. Med. 375:1834-1844 (November 2016), available at https://www.nejm.org/doi/10.1056/NEJMoa1607141 (visited on 10/19/23).

effects" and "the drug also inhibited duodenal and small bowel movements at the same time."[18]

35. Another study in 2017 reviewed the survey results from 10,987 patients and 851 physicians and found that "GI-related issues were the top two patient-reported reasons for GLP-1RA discontinuation in the past 6 months, with 'Made me feel sick' as the most frequently reported reason (64.4%), followed by 'Made me throw up' (45.4%)."[19] As explained above, these are symptoms of intestinal/bowel obstruction.

36. A 2019 study of the GLP-1RA drug dulaglutide identified adverse events for impaired gastric emptying.

37. In a September 2020 article funded and reviewed by Novo Nordisk, scientists affiliated with Novo Nordisk reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes. More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1.5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that "[f]or patients reporting severe adverse gastrointestinal reactions, it is advised to monitor renal function when initiating or escalating doses of oral semaglutide." For patients with other comorbidities, the study warned that "patients should be made aware of the occurrence of gastrointestinal adverse events

[18] Nakatani Y et al., *Effect of GLP-1 receptor agonist on gastrointestinal tract motility and residue rates as evaluated by capsule endoscopy*, 43(5) Diabetes & Metabolism, 430-37 (October 2017), available at https://www.sciencedirect.com/science/article/pii/S1262363617301076 (last visited on 10/25/23).
[19] Sikirica M et al., *Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes*, 10 Diabetes Metab. Syndr. Obes., 403-412 (September 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5630073/

with GLP-1RAs." The study further identified as one "key clinical take-home point" that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs."[20]

38. A July 2021 article funded and reviewed by Novo Nordisk considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that "gastrointestinal disturbances" were "well-known" side effects associated with semaglutide use. When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus up to 8% on the placebo group), vomiting in up to 11.5% of patients (versus up to 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus up to 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for GI-related adverse events, with some trials experiencing 100% discontinuation due to GI-related adverse events. The mean value of GR-related adverse events that led to discontinuation averaged 57.75%. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[21]

39. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[22]

40. An October 2022 study analyzed 5,442 GLP-1RA adverse gastrointestinal events. 32% were serious, including 40 deaths, 53 life-threatening conditions, and 772 hospitalizations. The primary events were nausea and vomiting. There were also adverse events for impaired gastric

[20] Mosenzon O, Miller EM, & Warren ML, *Oral semaglutide in patients with type 2 diabetes and cardiovascular disease, renal impairment, or other comorbidities, and in older patients*, Postgraduate Medicine (2020), 132:sup2, 37-47, available at https://doi.org/10.1080/00325481.2020.1800286 (visited on 9/26/23).
[21] Smits MM & Van Raalte DH (2021), *Safety of Semaglutide*, Front. Endocrinol., 07 July 2021, doi: 10.3389/fendo.2021.645563, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/ (last visited on 9/26/23).
[22] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).

emptying.[23]

41. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[24]

42. In February 2023, a longitudinal study of GLP-1RA (dulaglutide) reported adverse events for nausea and vomiting, and one adverse event of impaired gastric emptying.[25]

43. On March 28, 2023, a case study concluded that impaired gastric emptying is "a significant safety concern, especially since it is consistent with the known mechanism of action of the drug."[26]

44. In a May 2023 letter to the editor published in Acta Pharmaceutica Sinica B, the authors commented on GLP-1RAs, including Ozempic, Wegovy, and Rybelsus, and noted "adverse events such as increased risk of intestinal obstruction have been reported in diabetic patients, which is 4.5 times higher than those receiving other glucose control medications" based on a study published in 2020. The authors further noted a study published in 2022 "of 25,617 subjects demonstrated a 3.5-fold increase in the intestinal obstruction rate associated with GLP-1RA treatment."[27]

45. In May 2023, the risk of intestinal obstruction was specifically cited in the Lu study,

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[23] Shu, *Gastrointestinal adverse events associated with semaglutide: A pharmacovigilance study based on FDA adverse event reporting system*, Front. Public Health (Oct. 20, 2022). (https://doi.org/10.3389%2Ffpubh.2022.996179).

[24] Mirsha, *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).

[25] Chin, *Safety and effectiveness of dulaglutide 0.75 mg in Japanese patients with type 2 diabetes in real-world clinical practice: 36 month postmarketing observational study*, J Diabetes Investig (Feb. 2023) (https://doi.org/10.1111%2Fjdi.13932).

[26] Klein, Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report, Can J. Anesth (Mar. 28, 2023) (https://doi.org/10.1007/s12630-023-02440-3).

[27] Lu J et al., *A Potentially Serious Adverse Effect of GLP-1 Receptor Agonists*, 13(5) Acta Pharmaceutica Sinica B, 2291-2293 (May 2023), available at https://www.sciencedirect.com/science/article/pii/S2211383523000679 (last visited on 10/19/23); *see also* Faillie JL, et al., *Incretin-Based Drugs and Risk of Intestinal Obstruction Among Patients with Type 2 Diabetes*, Clinical Pharmacology Therapeutics vol. 11, Issue 1 (Jan. 2022), available at https://doi.org/10.1002/cpt.2430 (last visited on 10/19/23) and Gudin B, et al. *Incretin-based drugs and intestinal obstruction: a pharmacovigilance study*, 75(6) Therapies 641-47 (November-December 2020).

concluding that the use of GLP-1RAs may result in continuous increases in intestinal length, causing the intestines to "become as inelastic and fibrotic as a loose spring." The study indicated that intestinal blockage peaked after using GLP-1RAs for a year and a half, which the authors noted was longer than the duration of most clinical studies involving GLP-1RAs.[28]

46. On June 29, 2023, the American Society of Anesthesiologists ("ASA") warned that patients taking semaglutide and other GLP-1RAs should stop the medication at least a week before elective surgery because these medications "delay gastric (stomach) emptying" and "the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of food into the airways and lungs during general anesthesia and deep sedation." The ASA also warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[29]

47. News sources have identified the potential for serious side effects in users of Ozempic leading to hospitalization.[30] For example, NBC News reported in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said that five weeks into taking the medication she found herself unable to move off the bathroom floor

[28] Lu, J, et al., *A Potentially Serious Adverse Effect of GLP-1 Receptor Agonists*, 13(5) Acta Pharmaceutica Sinica B, 2291-2293 (May 2023), available at https://www.sciencedirect.com/science/article/pii/S2211383523000679 (last visited on 10/19/23).

[29] American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (last visited on 9/26/23).

[30] Penny Min, *Ozempic May Cause Potential Hospitalizations*, healthnews (June 26, 2023), available at https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/ (last visited on 9/26/23); Elizabeth Laura Nelson, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors*, Best Life (April 3, 2023), available at https://bestlifeonline.com/ozempic-side-effects-news/ (last visited on 9/26/23); Cara Shultz, *Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients*, People (July 26, 2023), available at https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833 (last visited on 9/26/23); CBS News Philadelphia, *Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn* (July 23, 2023), available at https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/ (last visited on 9/26/23).

because she had "vomited so much that [she] didn't have the energy to get up."[31]

48. A July 25, 2023 article in Rolling Stone magazine—"*Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell'*"—discussed the severe gastrointestinal effects of GLP-1RAs. In a statement to Rolling Stone, Novo Nordisk acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo Nordisk further stated that while "GLP-1 RAs are known to cause a delay in gastric emptying, … [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo Nordisk did not claim to have warned consumers about intestinal obstruction and its sequelae, or other severe GI issues.[32]

49. On July 25, 2023, CNN Health reported that patients taking GLP-1RAs are experiencing severe gastrointestinal reactions. One patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[33]

50. On July 26, 2023, a New York hospital published an article to its online health blog section noting that GLP-1RAs can delay or decrease the contraction of muscles that mix and propel contents in the gastrointestinal tract leading to delayed gastric emptying. One concern raised was that doctors often misdiagnose the patients' symptoms, meaning it may take a long time for

[31] Bendix A, Lovelace B Jr., *What it's like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds*, NBC News (Jan. 29, 2023), available at https://www.nbcnews.com/health/health-news/ozempic-wegovy-diabetes-weight-loss-side-effects-rcna66493 (last visited on 9/26/23).
[32] CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell'*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (last visited on 9/26/23).
[33] Brenca Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed,* CNN Health (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis (last visited on 9/26/23).

someone to be diagnosed correctly.[34]

51. In an article published on September 29, 2023, Dr. Caroline Apovian, a Professor of Medicine at Harvard Medical School, indicated that "her team had observed ileus in patients who had been prescribed semaglutide well before" Novo Nordisk's September 22, 2023 label change for Ozempic. In the same article, Dr. Dan Azagury, a Medical Director at Stanford University, explained that "ileus is a rare but potentially severe complication. So, we have to inform patients and we have to let them know that if they have these symptoms they need to check in with their physician."[35]

52. In an October 5, 2023, Research Letter published in the Journal of the American Medical Association ("JAMA"), the authors examined gastrointestinal adverse events associated with GLP-1RAs used for weight loss in clinical setting and reported that use of GLP-1RAs compared with use of bupropion-naltrexone was associated with increased risk of pancreatitis, gastroparesis, and bowel obstruction. The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of intestinal obstruction.[36]

53. Also on October 5, 2023, a medical journal reported a case of Mounjaro (tirzepatide) induced ileus. The authors concluded that the case "highlights the dangers of lack of ... monitoring of Mounjaro," especially in "patients who may be more susceptible to the gastrointestinal side effects of Mounjaro," and noted the need to "rais[e] awareness of potential

[34] *Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines*, Montefiore Health Blog article (released July 26, 2023), available at https://www.montefiorenyack.org/health-blog/what-you-need-know-about-gastroparesis (last visited on 9/26/2023).
[35] Mammoser G, *Ozempic Label Updated to Include Blocked Intestines as Potential Side Effect*, healthline (September 29, 2023), https://www.healthline.com/health-news/fda-updates-ozempic-label-to-include-blocked-intestines-as-potential-side-effect (last visited 10/20/23).
[36] Mohit Sodhi, et al., *Risk of Gastrointestinal Adverse Events Associated with Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss*, JAMA (published online October 5, 2023), available at https://jamanetwork.com/journals/jama/fullarticle/2810542 (last visited 10/19/23).

side effects" of the drug "and their severity."[37]

54. The medical literature listed above is not a comprehensive list, and there are additional case reports indicating that GLP-1RAs can cause intestinal/bowel obstruction, and its sequelae.

55. Defendant knew or should have known of the causal association between the use of GLP-1RAs and the risks of developing intestinal/bowel obstruction and its sequelae, but they ignored the causal association. Defendant's actual and constructive knowledge derived from its clinical studies, case reports, medical literature, including the medical literature and case reports referenced above in this Complaint.

56. On information and belief, Defendant not only knew or should have known that its GLP-1RAs cause delayed gastric emptying and inhibit intestinal motility, resulting in risks of intestinal/bowel obstruction, and its sequelae, but it may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that long-acting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[38]

D. Eli Lilly Failed to Warn of the Risk of Intestinal Obstruction and Its Sequelae from Mounjaro

57. The Prescribing Information for Mounjaro (the "label") discloses "Warnings and

[37] Kamini Rao et al., *Mounjaro: A Side Effect,* 7 J. Endocrine Soc. A69-70 (Oct.-Nov. 2023), available at https://academic.oup.com/jes/article/7/Supplement_1/bvad114.128/7290694 (last visited Nov. 16, 2023).
[38] Jensterle M et al., *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) Diabetes Obes. Metab. 975-984 (April 2023), available at https://dom-pubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944 (last visited on 9/26/23).

Precautions" and "Adverse Reactions" but does not warn that Mounjaro can cause ileus or intestinal obstruction.[39]

58. The Mounjaro label lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Mounjaro patients, but it does not include these adverse reactions in its "Warnings and Precautions" section, nor does it warn that these adverse reactions are symptoms of more severe conditions including ileus, intestinal obstruction and their sequelae. Intestinal obstruction is not mentioned at all in the label.

59. None of Defendant's additional advertising or promotional materials warned prescription providers or the general public of the risks of intestinal obstruction and its sequelae associated with GLP-1RAs.

60. Defendant knew or should have known of the causal association between the use of GLP-1RAs and the risks of developing intestinal obstruction and its sequelae. Defendant's actual and constructive knowledge derived from their clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced in this Complaint.

61. Upon information and belief, Defendant ignored the causal association between the use of GLP-1RAs and the risk of developing intestinal obstruction and its sequelae.

62. Eli Lilly's failure to disclose information that they possessed regarding the causal association between the use of GLP-1RAs and the risk of developing ileus and intestinal obstruction, rendered the warnings for Mounjaro inadequate.

63. On information and belief, as a result of Defendant's inadequate warnings, the medical community at large, and Plaintiff's prescribing physician(s) in particular, were not aware

[39] https://www.novo-pi.com/ozempic.pdf

that Mounjaro can cause ileus and intestinal obstruction, nor were they aware that the "common adverse reactions" listed on the label might be sequelae of ileus and intestinal obstruction.

64. On information and belief, had Defendant adequately warned Plaintiff's prescribing physician(s) that Mounjaro is causally associated with intestinal obstruction and its sequelae, then the physician's prescribing decision would have changed by not prescribing Mounjaro, or by monitoring Plaintiff's health for symptoms of intestinal obstruction and its sequelae, and discontinuing Mounjaro when the symptoms first started.

65. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from intestinal/bowel obstruction and its sequelae, which resulted in severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

FIRST CAUSE OF ACTION
(FAILURE TO WARN)

66. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

67. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Mounjaro drug that Plaintiff used.

68. Mounjaro was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendant.

69. At all relevant times, and at the times Mounjaro left Defendant's control, Defendant

knew or should have known that Mounjaro was unreasonably dangerous because the Defendant did not adequately warn of the risk of intestinal obstruction and its sequelae, especially when used in the form and manner as provided by Defendant.

70. Despite the fact that Defendant knew or should have known that Mounjaro caused unreasonably dangerous injuries, Defendant continued to market, distribute, and/or sell Mounjaro to consumers, including Plaintiff, without adequate warnings.

71. Despite the fact that Defendant knew or should have known that Mounjaro caused unreasonably dangerous injuries, Defendant continued to market Mounjaro to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

72. Defendant knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of its failure to provide adequate warnings, as set forth herein.

73. At all relevant times, given its increased safety risks, Mounjaro was not fit for the ordinary purposes for which it was intended.

74. At all relevant times, given its increased safety risks, Mounjaro did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

75. At all relevant times, Plaintiff was using Mounjaro for the purposes and in a manner normally intended.

76. The Mounjaro designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate warnings or instructions, as Defendant knew or should have known that this product created a risk of serious and dangerous injuries, including intestinal obstruction, and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendant failed to

adequately warn of said risks.

77. The Mounjaro designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendant knew or should have known of the risks of serious side effects, including intestinal obstruction and its sequelae, as well as other severe and permanent health consequences from Mounjaro, it failed to provide adequate warnings to users and/or prescribers of this product, and continued to improperly advertise, market and/or promote its product, Mounjaro.

78. The label for Mounjaro was inadequate because it did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Mounjaro, including the increased risk of intestinal/bowel obstruction, and its sequelae.

79. The label for Mounjaro was inadequate because it did not warn and/or adequately warn that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal/bowel obstruction, and its sequelae.

80. The label for Mounjaro was inadequate because it did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Mounjaro.

81. The label for Mounjaro was inadequate because it did not warn and/or adequately warn of the severity and duration of adverse effects, as the warnings given did not accurately reflect the symptoms or severity of the side effects.

82. Communications made by Defendant to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendant failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Mounjaro, including the increased risk of intestinal/bowel obstruction, and its sequelae.

83. Communications made by Defendant to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendant failed to warn and/or adequately warn that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal/bowel obstruction, and its sequelae.

84. Plaintiff had no way to determine the truth behind the inadequacies of Defendant's warnings as identified herein, and Plaintiff's reliance upon Defendant's warnings was reasonable.

85. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendant's warnings as identified herein, and his/her/their reliance upon Defendant's warnings was reasonable.

86. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of intestinal obstruction, and its sequelae, which is causally associated with Mounjaro, then the prescribing physician(s) would not have prescribed Mounjaro, and/or would have provided Plaintiff with adequate warnings regarding the dangers of Mounjaro, so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

87. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal/bowel obstruction, and its sequelae, the prescribing physician would not have prescribed Mounjaro, and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Mounjaro, so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

88. If Plaintiff had been warned of the increased risks of intestinal obstruction, and its sequelae, which are causally associated with Mounjaro, then Plaintiff would not have used Mounjaro and/or suffered from intestinal obstruction, and its sequelae.

89. If Plaintiff had been warned that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal/bowel obstruction, and its sequelae, then Plaintiff would not have used Mounjaro and/or suffered intestinal obstruction and its sequelae.

90. If Plaintiff had been warned of the increased risks of intestinal/bowel obstruction, and its sequelae, which are causally associated with Mounjaro, then Plaintiff would have informed Plaintiff's prescribing physician(s) that Plaintiff did not want to use Mounjaro.

91. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to use Mounjaro due to the risks of intestinal obstruction, and its sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Mounjaro.

92. By reason of the foregoing, Defendant has become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous product, Mounjaro.

93. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective product which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendant is therefore liable for the injuries sustained by Plaintiff.

94. Defendant's inadequate warnings for Mounjaro was an act that amounts to willful, wanton, and/or reckless conduct by Defendant.

95. Said inadequate warnings for Defendant's drug Mounjaro was a substantial factor in causing Plaintiff's injuries.

96. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including intestinal/bowel obstruction, and its sequelae, which

resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

97. As a result of the foregoing acts and omissions Plaintiff did incur medical, health, incidental, and related expenses, and requires and/or will require more health care and services. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SECOND CAUSE OF ACTION
(NEGLIGENT FAILURE TO WARN)

98. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

99. Georgia law imposes a duty on producers, manufacturers, distributors, lessors, and sellers of a product to exercise all reasonable care when producing, manufacturing, distributing, leasing, and selling their products.

100. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Mounjaro drug that Plaintiff used.

101. Mounjaro was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendant.

102. At all relevant times, and at the times Mounjaro left Defendant's control, Defendant knew or should have known that Mounjaro was unreasonably dangerous because it did not adequately warn of the risk of intestinal obstruction, and its sequelae, especially when used in the

form and manner as provided by Defendant.

103. Despite the fact that Defendant knew or should have known that Mounjaro caused unreasonably dangerous injuries, Defendant continued to market, distribute, and/or sell Mounjaro to consumers, including Plaintiff, without adequate warnings.

104. Despite the fact that Defendant knew or should have known that Mounjaro caused unreasonably dangerous injuries, Defendant continued to market Mounjaro to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

105. Defendant knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of its failure to provide adequate warnings, as set forth herein.

106. At all relevant times, given its increased safety risks, Mounjaro was not fit for the ordinary purposes for which it was intended.

107. At all relevant times, given its increased safety risks, Mounjaro did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

108. Defendant had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Mounjaro into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as intestinal obstruction, and its sequelae.

109. At all relevant times, Plaintiff was using Mounjaro for the purposes and in a manner normally intended.

110. The Mounjaro designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate warnings or

instructions, as Defendant knew or should have known that these product created a risk of serious and dangerous injuries, including intestinal obstruction, and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendant failed to adequately warn of said risks.

111. The Mounjaro designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendant knew or should have known of the risks of serious side effects, including intestinal obstruction, and its sequelae, as well as other severe and permanent health consequences from Mounjaro, it failed to provide adequate warnings to users and/or prescribers of this product, and continued to improperly advertise, market and/or promote its product, Mounjaro.

112. The label for Mounjaro was inadequate because it did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Mounjaro, including the increased risk of intestinal obstruction, and its sequelae.

113. The label for Mounjaro was inadequate because it did not warn and/or adequately warn that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal/bowel obstruction and its sequelae.

114. The label for Mounjaro was inadequate because it did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Mounjaro.

115. The label for Mounjaro was inadequate because it did not warn and/or adequately warn of the severity and duration of adverse effects, as the warnings given did not accurately reflect the symptoms or severity of the side effects.

116. Communications made by Defendant to Plaintiff and Plaintiff's prescribing

physician(s) were inadequate because Defendant failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Mounjaro, including the increased risk of intestinal obstruction, and its sequelae.

117. Communications made by Defendant to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendant failed to warn and/or adequately warn that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal obstruction, and its sequelae.

118. Plaintiff had no way to determine the truth behind the inadequacies of Defendant's warnings as identified herein, and Plaintiff's reliance upon Defendant's warnings was reasonable.

119. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendant's warnings as identified herein, and his/her/their reliance upon Defendant's warnings was reasonable.

120. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of intestinal obstruction and its sequelae, which are causally associated with Mounjaro, then the prescribing physician(s) would not have prescribed Mounjaro, and/or would have provided Plaintiff with adequate warnings regarding the dangers of Mounjaro, so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

121. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal obstruction and its sequelae, the prescribing physician would not have prescribed Mounjaro, and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Mounjaro, so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

122. If Plaintiff had been warned of the increased risks of intestinal obstruction and its sequelae, which are causally associated with Mounjaro, then Plaintiff would not have used Mounjaro and/or suffered from intestinal/bowel obstruction and its sequelae.

123. If Plaintiff had been warned that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal obstruction and its sequelae, then Plaintiff would not have used Mounjaro and/or suffered intestinal/bowel obstruction and its sequelae.

124. If Plaintiff had been warned of the increased risks of intestinal obstruction and its sequelae, which are causally associated with Mounjaro, then Plaintiff would have informed Plaintiff's prescribing physician(s) that Plaintiff did not want to use Mounjaro.

125. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to use Mounjaro due to the risks of intestinal obstruction and its sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Mounjaro.

126. By reason of the foregoing, Defendant has become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous product, Mounjaro.

127. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective product which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendant is therefore liable for the injuries sustained by Plaintiff.

128. Defendant's inadequate warnings for Mounjaro were acts that amount to willful, wanton, and/or reckless conduct by Defendant.

129. Said inadequate warnings for Defendant's drug Mounjaro was a substantial factor

in causing Plaintiff's injuries.

130. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including intestinal obstruction and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

131. As a result of the foregoing acts and omissions Plaintiff did incur medical, health, incidental, and related expenses, and requires and/or will require more health care and services. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

THIRD CAUSE OF ACTION
(FAILURE TO CONFORM TO REPRESENTATIONS)

132. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

133. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Mounjaro drug that Plaintiff used.

134. At all relevant times, Defendant expressly represented to Plaintiff and Plaintiff's prescribing physician(s) that Mounjaro was safe as an adjunct to diet and exercise to improve glycemic control and to reduce cardiovascular risks in adults with type 2 diabetes mellitus.

135. The aforementioned express representations were made to Plaintiff and Plaintiff's prescribing physician(s) by way of Mounjaro's labels, websites, advertisements, promotional materials, and through other statements.

136. As a result of Defendant's express representations, Plaintiff's prescribing physician(s) was/were induced to prescribe Mounjaro to Plaintiff, and Plaintiff was induced to use Mounjaro.

137. At all relevant times, Defendant reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Mounjaro based upon its express representations.

138. At all relevant times, Defendant reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Mounjaro based upon its express representations.

139. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of its increased risk of intestinal obstruction, and its sequelae, especially when the drug was used in the form and manner as provided by Defendant.

140. At all relevant times, Defendant knew or should have known that Mounjaro had not been sufficiently and/or adequately tested for safety.

141. The unreasonably dangerous characteristics of Mounjaro were beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drug's characteristics.

142. The unreasonably dangerous characteristics of Mounjaro were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drug's characteristics.

143. At the time Mounjaro left Defendant's control, Mounjaro did not conform to Defendant's express representations because Mounjaro was not safe to use as an adjunct to diet and exercise to improve glycemic control or to reduce cardiovascular risks in adults with type 2

diabetes mellitus, in that they were causally associated with increased risks of intestinal obstruction and its sequelae.

144. The express representations made by Defendant regarding the safety of Mounjaro were made with the intent to induce Plaintiff to use the product and/or Plaintiff's prescribing physician(s) to prescribe the product.

145. Defendant knew and/or should have known that by making the express representations to Plaintiff and/or Plaintiff's prescribing physician(s), it would be the natural tendency of Plaintiff to use Mounjaro, and/or the natural tendency of Plaintiff's prescribing physician(s) to prescribe Mounjaro.

146. Plaintiff and Plaintiff's prescribing physician(s), as well as members of the medical community, relied on the express representations of Defendant identified herein.

147. Had Defendant not made these express representations, Plaintiff would not have used Mounjaro and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Mounjaro.

148. Plaintiff's injuries and damages were directly caused by Defendant's breach of the aforementioned express representations.

149. Plaintiff's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff.

150. Accordingly, Defendant is liable to Plaintiff as a result of its breach of express representations.

151. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including intestinal/bowel obstruction and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental

anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

152. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendant's Mounjaro drug.

153. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

FOURTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

154. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

155. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Mounjaro drug that Plaintiff used.

156. At all relevant times, Defendant expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that Mounjaro was safe as an adjunct to diet and exercise to improve glycemic control and to reduce cardiovascular risks in adults with type 2 diabetes mellitus.

157. The aforementioned express warranties were made to Plaintiff and Plaintiff's prescribing physician(s) by way of Mounjaro's label, website, advertisements, promotional materials, and through other statements.

158. As a result of Defendant's express warranties, Plaintiff's prescribing physician(s)

was/were induced to prescribe Mounjaro to Plaintiff, and Plaintiff was induced to use Mounjaro.

159. At all relevant times, Defendant reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Mounjaro based upon its express warranties.

160. At all relevant times, Defendant reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Mounjaro based upon its express warranties.

161. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of its increased risk of intestinal obstruction, and its sequelae, especially when the drug was used in the form and manner as provided by Defendant.

162. At all relevant times, Defendant knew or should have known that Mounjaro had not been sufficiently and/or adequately tested for safety.

163. The unreasonably dangerous characteristics of Mounjaro were beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drug's characteristics.

164. The unreasonably dangerous characteristics of Mounjaro were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drug's characteristics.

165. At the time Mounjaro left Defendant's control, Mounjaro did not conform to Defendant's express warranties because Mounjaro was not safe to use as an adjunct to diet and exercise to improve glycemic control or to reduce cardiovascular risks in adults with type 2 diabetes mellitus, in that it was causally associated with increased risks of intestinal obstruction and its sequelae.

166. The express warranties made by Defendant regarding the safety of Mounjaro were made with the intent to induce Plaintiff to use the product and/or Plaintiff's prescribing physician(s) to prescribe the product.

167. Defendant knew and/or should have known that by making the express warranties to Plaintiff and/or Plaintiff's prescribing physician(s), it would be the natural tendency of Plaintiff to use Mounjaro, and/or the natural tendency of Plaintiff's prescribing physician(s) to prescribe Mounjaro.

168. Plaintiff and Plaintiff's prescribing physician(s), as well as members of the medical community, relied on the express warranties of Defendant identified herein.

169. Had Defendant not made these express warranties, Plaintiff would not have used Mounjaro and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Mounjaro.

170. Plaintiff's injuries and damages were directly caused by Defendant's breach of the aforementioned express warranties.

171. The filing of this Complaint serves as adequate notice of Defendant's breach under the circumstances of this case, including the fact that Defendant had actual and/or constructive knowledge that Mounjaro was unreasonably dangerous because of its increased risk of intestinal obstruction, and its sequelae, and that pre-litigation notice would not have provided Defendant an opportunity to cure the breach and would have been wholly futile.

172. Plaintiff's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff.

173. Accordingly, Defendant is liable to Plaintiff as a result of its breach of express warranties.

174. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including intestinal/bowel obstruction, and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

175. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendant's Mounjaro drug.

176. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

FIFTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY IN TORT)

177. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

178. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Mounjaro drug that Plaintiff used.

179. Mounjaro was expected to and did reach the usual consumers, handlers, and persons encountering said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant.

180. At all relevant times, Defendant impliedly warranted to Plaintiff, Plaintiff's prescribing physician(s), and the medical community that Mounjaro was of merchantable quality and safe and fit for its ordinary purpose.

181. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of the increased risk of intestinal obstruction, and its sequelae, especially when the drug was used in the form and manner as provided by Defendant.

182. At all relevant times, Defendant knew or should have known that Mounjaro had not been sufficiently and/or adequately tested for safety.

183. At the time Mounjaro left Defendant's control, Mounjaro did not confirm to Defendant's implied warranty and was unfit for its ordinary purpose because Defendant failed to provide adequate warnings of the drug's causal association with increased risk of intestinal obstruction, and its sequelae.

184. At all relevant times, Defendant reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Mounjaro for use by their patients to improve glycemic control in adults with type 2 diabetes, to reduce cardiovascular risk, and/or to promote weight loss.

185. At all relevant times, Defendant reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Mounjaro for its ordinary purpose.

186. Despite the fact that Defendant knew or should have known that Mounjaro caused unreasonably dangerous injuries, such as intestinal obstruction, and its sequelae, Defendant continued to market, distribute, and/or sell Mounjaro to consumers, including Plaintiff, without adequate warnings.

187. The unreasonably dangerous characteristics of Mounjaro were beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drug's characteristics.

188. The unreasonably dangerous characteristics of Mounjaro were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drug's characteristics.

189. Plaintiff reasonably relied on Defendant' implied warranty of merchantability relating to Mounjaro's safety and efficacy.

190. Plaintiff reasonably relied upon the skill and judgment of Defendant as to whether Mounjaro was of merchantable quality and safe and fit for its intended use.

191. Upon information and belief, Plaintiff's prescribing physician(s) relied on Defendant's implied warranty of merchantability and fitness for the ordinary use and purpose relating to Mounjaro.

192. Upon information and belief, Plaintiff's prescribing physician(s) reasonably relied upon the skill and judgment of Defendant as to whether Mounjaro was of merchantable quality and safe and fit for its intended use.

193. Had Defendant not made these implied warranties, Plaintiff would not have used Mounjaro, and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Mounjaro, and/or would have altered his/her/their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Mounjaro, to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

194. Defendant herein breached the aforesaid implied warranty of merchantability because the drug Mounjaro was not fit for its intended purpose.

195. Defendant's breaches of implied warranty of merchantability were a substantial factor in causing Plaintiff's injuries.

196. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including intestinal/bowels obstruction, and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

197. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SIXTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

198. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

199. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Mounjaro drug that Plaintiff used.

200. Mounjaro was expected to and did reach the usual consumers, handlers, and persons encountering said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant.

201. At all relevant times, Defendant impliedly warranted to Plaintiff, Plaintiff's prescribing physician(s), and the medical community that Mounjaro was of merchantable quality and safe and fit for its ordinary purpose.

202. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of the increased risk of intestinal obstruction, and its sequelae, especially when the drug was used in the form and manner as provided by Defendant.

203. At all relevant times, Defendant knew or should have known that Mounjaro had not been sufficiently and/or adequately tested for safety.

204. At the time Mounjaro left Defendant's control, Mounjaro did not conform to Defendant's implied warranty and was unfit for its ordinary purpose because Defendant failed to provide adequate warnings of the drug's causal association with increased risk of intestinal obstruction, and its sequelae.

205. At all relevant times, Defendant reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Mounjaro for use by their patients to improve glycemic control in adults with type 2 diabetes, to reduce cardiovascular risk, and/or to promote weight loss.

206. At all relevant times, Defendant reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Mounjaro for its ordinary purpose.

207. Despite the fact that Defendant knew or should have known that Mounjaro caused unreasonably dangerous injuries, such as intestinal obstruction, and its sequelae, Defendant continued to market, distribute, and/or sell Mounjaro to consumers, including Plaintiff, without adequate warnings.

208. The unreasonably dangerous characteristics of Mounjaro were beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drug's characteristics.

209. The unreasonably dangerous characteristics of Mounjaro were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drug's characteristics.

210. Plaintiff reasonably relied on Defendant's implied warranty of merchantability relating to Mounjaro's safety and efficacy.

211. Plaintiff reasonably relied upon the skill and judgment of Defendant as to whether Mounjaro was of merchantable quality and safe and fit for its intended use.

212. Upon information and belief, Plaintiff's prescribing physician(s) relied on Defendant's implied warranty of merchantability and fitness for the ordinary use and purpose relating to Mounjaro.

213. Upon information and belief, Plaintiff's prescribing physician(s) reasonably relied upon the skill and judgment of Defendant as to whether Mounjaro was of merchantable quality and safe and fit for its intended use.

214. Had Defendant not made these implied warranties, Plaintiff would not have used Mounjaro, and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Mounjaro, and/or would have altered his/her/their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Mounjaro, to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

215. Defendant herein breached the aforesaid implied warranty of merchantability because the drug Mounjaro was not fit for its intended purpose.

216. Defendant's breaches of implied warranty of merchantability were a substantial factor in causing Plaintiff's injuries.

217. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including intestinal/bowel obstruction, and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

218. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SEVENTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

219. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

220. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Mounjaro drug that Plaintiff used.

221. At all relevant times, Defendant knew or should have known that Mounjaro had not been adequately and/or sufficiently tested for safety.

222. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of the increased risk of intestinal obstruction, and its sequelae, especially when the drug was used in the form and manner as provided by Defendant.

223. Defendant had a duty to disclose material information about Mounjaro to Plaintiff and Plaintiff's prescribing physician(s), namely that Mounjaro is causally associated with increased risk of intestinal obstruction, and its sequelae, because Defendant has superior knowledge of the drug and its dangerous side effects, this material information is not readily available to Plaintiff or Plaintiff's prescribing physician(s) by reasonable inquiry, and Defendant knew or should have known that Plaintiff and Plaintiff's prescribing physician would act on the basis of mistaken knowledge.

224. Nonetheless, Defendant consciously and deliberately withheld and concealed from Plaintiff's prescribing physician(s), Plaintiff, the medical and healthcare community, and the general public this material information.

225. Although the Mounjaro label lists nausea, vomiting, diarrhea, abdominal pain, constipation, as the most common adverse reactions reported in patients using Mounjaro, it does not mention intestinal obstruction as a risk of taking Mounjaro, nor does it disclose intestinal obstruction as a chronic condition that can result as a consequence of taking Mounjaro.

226. Defendant's promotional website for Mounjaro similarly does not disclose that Mounjaro is causally associated with increased risk of intestinal obstruction, and its sequelae.

227. Defendant's omissions and concealment of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and adult type 2 diabetes patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Mounjaro for treatment of adults with type 2 diabetes.

228. Defendant knew or should have known that Plaintiff's prescribing physician(s) would prescribe, and Plaintiff would use, Mounjaro without the awareness of the risks of serious

side effects, including intestinal/bowel obstruction, and its sequelae.

229. Defendant knew that Plaintiff and Plaintiff's prescribing physicians (s) had no way to determine the truth behind Defendant's misrepresentations and concealments surrounding Mounjaro, as set forth herein.

230. Upon information and belief, Plaintiffs prescribing physician(s) justifiably relied on Defendant's material misrepresentations, including the omissions contained therein, when making the decision to dispense, provide, and prescribe Mounjaro.

231. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of intestinal obstruction, and its sequelae causally associated with Mounjaro, they would not have prescribed Mounjaro, and/or would have provided Plaintiff with adequate information regarding the increased risk of intestinal obstruction, and its sequelae causally associated with Mounjaro, to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

232. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal obstruction and its sequelae, they would not have prescribed Mounjaro, and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Mounjaro, to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

233. Plaintiff justifiably relied on Defendant's material misrepresentations, including the omissions contained therein, when making the decision to purchase and/or use Mounjaro.

234. Had Plaintiff been informed of the increased risks causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered intestinal/bowel obstruction and its sequelae.

235. Defendant's fraudulent concealments were a substantial factor in causing Plaintiff's injuries.

236. As a direct and proximate result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries, including intestinal/bowel obstruction and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

237. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

EIGHTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

238. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

239. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Mounjaro drug that Plaintiff used.

240. At all relevant times, Defendant knew or should have known that Mounjaro had not been adequately and/or sufficiently tested for safety.

241. At all relevant times, Defendant knew or should have known of the serious side effects of Mounjaro, including intestinal obstruction, and its sequelae.

242. At all relevant times, Defendant knew or should have known that Mounjaro was not safe to improve glycemic control in adults with type 2 diabetes, to reduce cardiovascular risk in patients with type 2 diabetes, or to promote weight loss, given its increased risk of intestinal/bowel obstruction, and its sequelae.

243. Nonetheless, Defendant made material misrepresentations to Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Mounjaro.

244. Defendant represented affirmatively and by omission on advertisements and on the labels of Mounjaro that Mounjaro was safe and effective drug for treatment of adults with type 2 diabetes, despite being aware of increased risks of intestinal obstruction and its sequelae causally associated with using Mounjaro.

245. Defendant was aware or should have been aware that its representations were false or misleading, and it knew that it were concealing and/or omitting material information from Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community, and the general public.

246. Defendant's misrepresentations of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and adult type 2 diabetes patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Mounjaro for treatment of adults with type 2 diabetes.

247. Upon information and belief, Plaintiff's prescribing physician(s) had no way to determine the truth behind Defendant's false and/or misleading statements, concealments and omissions surrounding Mounjaro, and Plaintiff's prescribing physician(s) reasonably relied on false and/or misleading facts and information disseminated by Defendant, including Defendant's omissions of material facts which Plaintiff's prescribing physician(s) had no way to know were omitted.

248. Upon information and belief, Plaintiff's prescribing physician(s) justifiably relied on Defendant's material misrepresentations, including omissions contained therein, when making the decision to prescribe Mounjaro to Plaintiff.

249. Upon information and belief, had Plaintiff's prescribing physician(s) been informed of the increased risk of intestinal obstruction, and its sequelae causally associated with Mounjaro, Plaintiff's prescribing physician(s) would not have prescribed Mounjaro, and/or would have provided Plaintiff with adequate information regarding safety of Mounjaro, to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

250. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal obstruction and its sequelae, they would not have prescribed Mounjaro, and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Mounjaro, so that Plaintiff can make an informed decision regarding Plaintiff's use of Mounjaro.

251. Plaintiff had no way to determine the truth behind Defendant's false and/or misleading statements, concealments and omissions surrounding Mounjaro, and Plaintiff reasonably relied on false and/or misleading facts and information disseminated by Defendant,

including Defendant's omissions of material facts which Plaintiff had no way to know were omitted.

252. Plaintiff justifiably relied on Defendant's material misrepresentations, including omissions contained therein, when making the decision to accept, purchase and/or consume Mounjaro.

253. Had Plaintiff been told of the increased risk of intestinal obstruction, and its sequelae causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered intestinal/bowel obstruction, and its sequelae.

254. Had Plaintiff been told of the lack of sufficient and/or appropriate testing of Mounjaro for safety risks, including intestinal obstruction and its sequelae, Plaintiff would not have used Mounjaro and/or suffered intestinal/bowel obstruction, and its sequelae.

255. As a direct and proximate result of these false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries, including intestinal/bowel obstruction, and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

256. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

NINTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

257. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

258. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Mounjaro drug that Plaintiff used.

259. At all relevant times, Defendant knew or should have known that Mounjaro had not been adequately and/or sufficiently tested for safety.

260. At all relevant times, Defendant knew or should have known of the serious side effects of Mounjaro, including intestinal obstruction, and its sequelae.

261. Defendant had a duty to disclose material information about Mounjaro to Plaintiff and Plaintiff's prescribing physician(s) that Mounjaro is causally associated with increased risk of intestinal obstruction, and its sequelae, because Defendant held a special expertise with respect to Mounjaro, Plaintiff, as a user of Mounjaro, had a special relationship of trust with Defendant, and Defendant knew that its statements regarding the risks causally associated with Mounjaro would be relied on by users of Mounjaro.

262. At all relevant times, Defendant knew or should have known of the serious side effects of Mounjaro, including intestinal obstruction, and its sequelae.

263. Nonetheless, Defendant made material misrepresentations and omissions and/or concealments to Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Mounjaro.

264. Defendant represented affirmatively and by omission on advertisements and on the label of Mounjaro that Mounjaro was safe and effective drug for treatment of adults with type 2 diabetes, despite being aware of the increased risks of intestinal obstruction, and its sequelae

causally associated with using Mounjaro.

265. Defendant was aware or should have been aware that its representations were false or misleading and/or knew that Defendant was concealing and/or omitting material information from Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community, and the general public.

266. Defendant knew that Plaintiff and Plaintiff's prescribing physicians(s) had no way to determine the truth behind Defendant's misrepresentations and concealments surrounding Mounjaro, as set forth herein.

267. Upon information and belief that Plaintiff's prescribing physician(s) justifiably relied on Defendant's material misrepresentations, including the omissions contained therein, when making the decision to prescribe Mounjaro to Plaintiff.

268. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of intestinal obstruction, and its sequelae causally associated with Mounjaro, they would not have prescribed Mounjaro, and/or would have provided Plaintiff with adequate information regarding safety of Mounjaro, so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

269. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including intestinal obstruction, and its sequelae, they would not have prescribed Mounjaro, and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Mounjaro, so that Plaintiff can make an informed decision regarding Plaintiff's use of Mounjaro.

270. Plaintiff reasonably relied on the false and/or misleading facts and information

disseminated by Defendant, which included Defendant's omissions of material facts which Plaintiff had no way to know were omitted.

271. Had Plaintiff been told of the increased risk of intestinal obstruction, and its sequelae causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered intestinal/bowel obstruction, and its sequelae.

272. Defendant's misrepresentations and omissions of material facts amount to willful, wanton, and/or reckless conduct.

273. As a direct and proximate result of these false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including intestinal/bowel obstruction, and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

274. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by

law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendant, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendant and deter future similar conduct;

3. Awarding Plaintiff the costs of these proceedings; and

4. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: May 2, 2025

Respectfully Submitted,

/s/ Parvin K. Aminolroaya

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